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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.FUS01	6766

22865 7590 07/28/2003

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EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

21

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-21

Office Action Summary

Applicati n No.

09/475,721

Applicant(s)

REIMINK ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-20,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-20,31-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Rejections Withdrawn

1. The 35 U.S.C. 102(b) and 103(a) rejections in Paper # 14 (mailed 08/14/02) have been withdrawn due to Applicant's amendment in Paper # 19 (filed 04/25/03).

New Rejections

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-8, 10-19, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Pietsch et al.

Pietsch et al. teaches a medical device comprising a composite having an inorganic substrate (support ring) and a polymer (plastic) covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device (a heart valve whereby the support ring and the cusps are formed integrally as a result of the plastic skin, from which the cusps are formed, also enclosing the support ring, thus providing the form or shape of the device). The substrate (support ring) is made out of metal (stainless steel, titanium) or ceramics (column 3, lines 30-55). The polymer is crosslinked polydimethylsiloxane (silicone rubber), having high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness (column 4, lines 55-68 and column 5, lines 1-15). Crosslinked polyether-urethanes are also taught to be suitable with a low Shore A hardness and a high breaking strength (column 4, lines 20-55).

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Since Pietsch et al. teaches that the crosslinked silicone rubber (polydimethylsiloxane) has high fatigue strength in alternate bending, a high breaking strength of at least 8 N/mm^2 at a low Shore A hardness of 25-35, and an elongation at break of more than 400 %, in the absence of a showing to the contrary, the examiner has taken the position that the composite can be bent by at least 100 degrees while remaining elastic, by about 180 degrees without extending the component beyond its elastic limit, and by about 60 degrees for about 40 million cycles to about 400 million cycles without significant structural failure.

Claim Rejections - 35 USC § 103

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pietsch et al. in view of Sumimoto Electric Co.

Pietsch et al. has been discussed above, and teaches the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device. Pietsch et al. fails to teach a diamond-like carbon coating over at least a portion of the silicone or urethane polymer.

Sumimoto Electric Co. teaches that coating by carbon or diamond of an artificial heart valve comprising polymer such as silicone polymer, polyurethane or PTFE gives the valve good antithrombosis property and good durability (abstract) thus providing the advantage and hence the motivation to coat the heart valve of Pietsch et al. with carbon or diamond in order to provide antithrombogenicity and improved durability.

Both Sumimoto Electric Co. and Pietsch et al. are directed to an artificial heart valve.

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5. Claims 9, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pietsch et al. in view of MacGregor.

Pietsch et al. has been discussed above, and teaches the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device.

Pietsch et al. fails to teach that the polymer is rigid.

MacGregor teaches a heart valve made from a combination of rigid polymer(ic material), metal or ceramic and carbon. The metal substrate is given as an example (column 3, lines 20-30 and column 4, lines 30-50). The thickness of the rigid porous rigid plastic coating is taught to be about 20 to 300 microns and the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength. The polymer may be attached by flowing into the metal substrate thus forming a barb or anchor (column 5, lines 5-50).

Both Pietsch et al. and MacGregor are directed to an artificial heart valve.

Because MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength, it would have been obvious to one of ordinary skill in the art to have used the combination of rigid polymer, metal or ceramic and carbon of MacGregor in the invention of Cromie in order to obtain a heart valve with the desired fatigue endurance limit.

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Response to Arguments

6. Applicant's arguments with respect to claims 1-3, 5-20, 31-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

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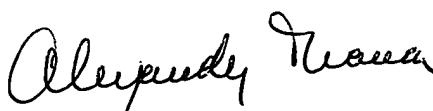
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH

Sow-Fun Hon

07/18/03



ALEXANDER S. THOMAS
PRIMARY EXAMINER